

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

# 7  
Harry  
Jan. 12, 02

In re Application of:

Group No.: 1644

David WALLACH et al

Examiner: P. Gambel

Appln. No.: 08/476,862

Filed: June 7, 1995

For: TNF LIGANDS

Atty. Docket: WALLACH=12A



DECLARATION OF BIOLOGICAL MATERIAL DEPOSIT

Honorable Commissioner for Patents  
Washington, D.C. 20231

Sir:

1. Yeda Research and Development Co. Ltd., a corporation having a principal place of business at Rehovot 76100, Israel, (hereinafter "Yeda") hereby certifies that it is the depositor of the biological material referred to herein and is also the assignee of the entire right, title and interest of the above-identified United States Patent application by virtue of assignments from the inventors of the above-identified United States Patent application. Assignments from four of the five inventors were recorded March 19, 1996, at Reel 7853, Frame 0762, copies of which are attached hereto, and an assignment from the fifth inventor (Hartmut Engelmann) was submitted for recordation on October 11, 2000, a copy of which is also attached hereto. The attached copies establish a chain of title from each of the inventors to Yeda. The undersigned (whose title is supplied below) is empowered to sign this document on behalf of the depositor/assignee.

2. The following biological material, referred to in the specification of this application, has been deposited and has received the following accession number(s) by the depository:

Monoclonal antibody 67  
strain

I-1368  
accession number

3. The name and address of the depository is:

Collection National de Cultures de  
Microorganismes (CNCM), Institut Pasteur  
25, rue de Docteur Roux,  
75724 Paris Cedex 15, France.

4. The above deposit of monoclonal antibody 67 was made on October 11, 1993, which was before the filing date of Israeli application 107,267 filed October 12, 1993. The original deposit was a non-Budapest deposit as the depository at that time did not accept hybridomas under the Budapest Treaty. However, CNCM acquired status of international depository authority for hybridomas on January 31, 1996. The originally deposited material was converted to a Budapest Treaty Deposit by request received on December 17, 1996. A copy of the International Receipt Form, dated March 31, 2000, acknowledging this deposit as a Budapest Treaty deposit is attached hereto. The deposit date of October 11, 1993, was after the filing date of the first application upon which reliance is made for this monoclonal antibody, i.e., Israeli application 94,039 filed April 6, 1990. A verified statement pursuant to 37 CFR 1.804(b) will be filed in due course, stating that the biological

material which was deposited is a biological material specifically identified in the application as filed.

5. The biological material deposited is capable of self-replication, either directly or indirectly, and

XXX The originally deposited biological material described above has been accepted under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter Budapest Treaty) and therefore the filing of a viability statement is unnecessary (37 CFR 1.807(b)).

XXX Statements that the biological material deposited with the above named depository was viable and was capable of reproduction on the date of the original deposit, as well as at the time of conversion to a Budapest Treaty deposit, are attached. Such are executed by:

(complete a, b or c below)

- a. XX the depository
- b. — the applicant
- c. — a competent third party

6. With respect to the permanence of the biological material deposit:

XXX The depository is an official depository in accordance with the Budapest Treaty and the deposit of the biological material described above has been accepted under the Budapest Treaty such that samples will be

available beyond the enforceable life of the patent for which the deposit was made.

— The contract with the above-mentioned depository with respect to the deposited biological material provides that the depository will afford permanence of the deposit for at least 30 years and at least 5 years after the most recent request for the furnishing of a sample of the deposit was received by the depository, samples being available beyond the enforceable life of the patent for which the deposit was made.

I affirm that should the depositor be notified by the depository that it either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, depositor will proceed in accordance with 37 CFR \$1.805.

7. With respect to availability of the biological material, I affirm that the deposit has been made under conditions that assure that (a) access to the deposit will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR \$1.14 and 35 USC \$122, and (b) subject to 37 CFR \$1.808(b), all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

In re Appln. No. 08/476,862  
Declaration of Biological  
Culture Deposit

7. I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Paulina Ben-Ami, Vice President  
Type or Print Name of Person Signing

12 October 2000  
Date

Paulina Ben. Ami  
signature

XX Inventor  
Assignee of Complete Interest  
Person Authorized to Sign on  
Behalf of the Depositor/Assignee

(complete the following if applicable)

YEDA RESEARCH AND DEVELOPMENT CO. LTD.  
Type Name of Depositor/Assignee

P.O. Box 95, Rehovot 76100, ISRAEL  
Address of Depositor/Assignee

Title of Person Authorized to Sign  
on Behalf of Depositor/Assignee:

AGREEMENT OF 25 AUGUST 1978, AS AMENDED ON 4 OCTOBER 1982, BETWEEN EUROPEAN PATENT ORGANISATION AND THE COLLECTION NATIONALE DE CULTURES DE MICROORGANISMES (C.N.C.M.), INSTITUT PASTEUR, PARIS, CONCERNING THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE UNDER RULES 28 AND 28a OF THE EUROPEAN PATENT CONVENTION.

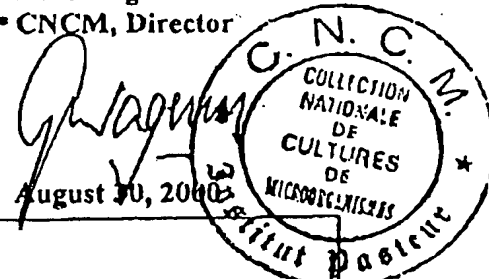
~~RECEIPT OF THE DEPOSIT OF MICROORGANISMS~~  
~~FOR THE PURPOSES OF PATENT PROCEDURE~~

## INTERNATIONAL FORM

Copy of the Original Receipt

TO  
**YEDA RESEARCH AND  
 DEVELOPMENT Co.Ltd.**  
 at the Weizmann Institute  
 P.O. Box 95  
 REHOVOT 76100 ISRAEL  
 NAME AND ADDRESS  
 OF DEPOSITOR

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT  
 issued pursuant to ~~Rule 1.1~~ by the ~~Patent~~ (a) by the  
 INTERNATIONAL DEPOSITARY AUTHORITY  
 identified at the bottom of this page **CNCM, Director**



## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
 DEPOSITOR:

67

Accession number given by the  
 INTERNATIONAL DEPOSITARY AUTHORITY:

I - 1368

**CERTIFICATE CONFORME  
 A L'ORIGINAL**

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒ a scientific description

☒ a proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above,  
 which was received by it on (date of the original deposit)

October 11, 1993

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
 Depositary Authority on (date of the original deposit) and  
 a request to convert the original deposit to a deposit under the ~~Bilateral~~ **Bilateral Agreement**  
 was received by it on (date of receipt of request for conversion)

## V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: **CNCM**  
 Collection Nationale  
 de Cultures de Microorganismes  
 Address: **INSTITUT PASTEUR**  
 28, Rue du Docteur Roux  
 F-75724 PARIS CEDEX 15

Signature(s) of person(s) having the power  
 to represent the International Depositary  
 Authority or of authorized official(s):

Date: November 24, 1993

*Y. Cerisier*

1. ~~XX~~  
 authority was accepted.

~~BUDAPEST TREATY ON THE INTERNATIONAL~~  
~~RECOGNITION OF THE DEPOSIT OF MICROORGANISMS~~  
~~FOR THE PURPOSES OF PATENT PROCEDURE~~

INTERNATIONAL FORM

TO

Mr Enrica DRAGHI  
INTER-LAB Ltd.  
Science-Based Industrial Park  
Kiryat Weizmann,  
NESS ZIONA  
76110, ISRAEL

VIABILITY STATEMENT  
issued pursuant to ~~Rule 10.3.b~~ Point 24 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: YEDA RESEARCH AND DEVELOPMENT Co.Ltd. Address: at the Weizmann Institute of Science P.O. Box 95 REHOVOT 76100 ISRAEL	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: <b>I - 1368</b> Date of the deposit or of the transfer: <b>October 11, 1993</b>
III. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested on <b>October 12, 1993</b> <div data-bbox="82 1291 162 1354"><input checked="" type="checkbox"/></div> <sup>3</sup> viable <div data-bbox="82 1375 162 1438"><input type="checkbox"/></div> <sup>3</sup> no longer viable	

- <sup>1</sup> Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).  
Point 24.b)ii) and iii)
- <sup>2</sup> In the cases referred to in ~~Rule 10.3(a) (i) and (ii)~~, refer to the most recent viability test.
- <sup>3</sup> Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED<sup>4</sup>

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name:

**CNCM**

Collection Nationale  
de Cultures de Microorganismes

Address:

**INSTITUT PASTEUR**

28, Rue du Docteur Roux  
F-75724 PARIS CEDEX 15  
FRANCE

Signature(s) of person(s) having the power  
to represent the International Depositary  
Authority or of authorized official(s):

Date: **Done in Paris on November 24, 1993**

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.



**Simona OZDEN**  
Scientific Advisor of the CNCM  
for the Cell-lines



**Yvonne CERISIER**  
Administrative Director of the CNCM



BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

Certified

Copy of the Original Receipt

TO :

Yeda Research and Development Co. Ltd  
at the Weizmann Institute of Science  
P.O.Box 95  
Rehovot 76100, Israel

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT  
issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this page



NAME AND ADDRESS  
OF DEPOSITOR

<b>I. IDENTIFICATION OF THE MICROORGANISM</b>	
Identification reference given by the DEPOSITOR :  <b>67</b>	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY :  <b>I - 1368</b>
<b>II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION</b>	
The microorganism identified under I above was accompanied by :  <input checked="" type="checkbox"/> a scientific description  <input checked="" type="checkbox"/> a proposed taxonomic designation  (Mark with a cross where applicable)	
<b>III. RECEIPT AND ACCEPTANCE</b>	
This International Depositary Authority accepts the microorganism identified under I above, which was received by it on <b>31 January 1996</b> (date of the original deposit) <sup>1</sup>	
<b>IV. RECEIPT OF REQUEST FOR CONVERSION</b>	
The microorganism identified under I above was received by this International Depositary Authority on <b>11 October 1993</b> (date of the original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on <b>17 December 1996</b> (date of receipt of request for conversion)	
<b>V. INTERNATIONAL DEPOSITARY AUTHORITY</b>	
Name :  <b>CNCM</b> Collection Nationale de Cultures de Microorganismes  Address :  <b>INSTITUT PASTEUR</b> 28, Rue du Docteur Roux F-75724 PARIS CEDEX 15	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s) :  <b>Georges WAGENER</b> Director, CNCM  Date : <b>31 March 2000</b>

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international  
depository authority was acquired.

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO :

Mr. Henry Einav,  
Director of Corporate Patent Department,  
Inter-Lab Ltd,  
Science-based Industrial Park,  
Kiryat Weizmann,  
Ness-Ziona 76100,  
Israel

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY STATEMENT  
IS ISSUED

VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name : <b>Yeda Research and Development Co. Ltd. at the Weizmann Institute of Science</b></p> <p>Address : <b>P.O.Box 95, Rehovot 76100, Israel</b></p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY :</p> <p style="text-align: center; font-size: 1.2em;"><b>I - 1368</b></p> <p>Date of the deposit or of the transfer <sup>1</sup> :</p> <p style="text-align: center;"><b>31 January 1996</b></p>
<p>III. VIABILITY STATEMENT</p> <p>The viability of the microorganism identified under II above was tested on <b>05 February 1997</b> <sup>2</sup> . On that date, the said microorganism was</p> <div style="display: flex; margin-top: 10px;"> <div style="margin-right: 10px;"> <input checked="" type="checkbox"/> <sup>3</sup> </div> <div> <p>viable</p> </div> </div> <div style="margin-top: 10px;"> <input type="checkbox"/> <sup>3</sup> </div> <div> <p>no longer viable</p> </div>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a)(ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED<sup>4</sup>

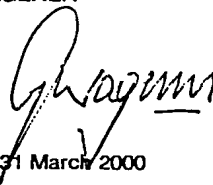
V. INTERNATIONAL DEPOSITARY AUTHORITY

Name : **CNCM**  
Collection Nationale  
de Cultures de Microorganismes

Address : **INSTITUT PASTEUR**  
25, Rue du Docteur Roux  
75724 PARIS CEDEX 15  
FRANCE

Signature(s) of person(s) having the power  
to represent the International Depositary  
Authority or of authorized official(s) :

Georges WAGENER  
Director, CNCM



Date : 31 March 2000

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.